

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Paul T. GARDINER et al.
Serial No. : 10/799,038
Filed : March 11, 2004
For : Food Supplement for Increasing Lean Muscle Mass and Strength
Examiner : Frank Choi
Art Unit : 1616

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF MR. KEN CLEMENT UNDER 37 C.F.R. §1.132

Sir:

I, Mr. Ken Clement, do hereby declare the following:

- 1) I have read and understand the subject matter of the pending U.S. patent application serial no. 10/799,038, titled "Food Supplement for Increasing Lean Mass and Strength", filed March 11, 2004.
- 2) It is my opinion that a person of ordinary skill in the art in the fields of nutrition and nutritional supplementation as of the date of filing of U.S. patent application serial no. 10/799,038 would have at least a bachelor's degree in chemistry, biochemistry, biology or related discipline or a person with comparable experience gained through other means having at least 3 years of experience in the fields of nutrition and nutritional supplementation.

- 3) I am one of ordinary skill in the art with respect to the fields of nutrition and nutritional supplementation. A copy of my *Curriculum Vitae*, evidencing my experience in these fields, is attached herewith.
- 4) I am the Director of Research and Development at Iovate Health Sciences Research Inc.. In this capacity, I am responsible for the research and development of new products in the fields of nutrition and nutritional supplementation.
- 5) I have been formulating compositions for nutritional supplements for use in, but not limited to, the health and wellness industry and the bodybuilding industry for at least 7 years.
- 6) I am also a competitive bodybuilder and a consumer of nutritional supplements for use in bodybuilding.
- 7) I have won numerous prizes¹ for my achievements in bodybuilding.
- 8) I have read and understand the Office Action dated October 21, 2008 ("Office Action") in connection with the present application.
- 9) I have read and understand the claims that counsel seeks to submit.
- 10) The independent method claim is:

A method for supplementing the diet of a human to enhance muscle size and strength, comprising orally administering a dietary supplement comprising admixed effective amounts of:

a protein selected from the group consisting of whey protein and whey peptides,

a compound which mimics or enhances insulin activity, said compound being selected from the group consisting of myo-inositol, d-myo-inositol, cis-

¹ 1st place Heavyweight Division, 2005 Healthy Body Expo; 1st place, 2003 Muscletech Bodybuilding Championship; and 2nd place, 1998 Northern Cup Challenge.

inositol, epinositol, allo-inositol, muco-inositol, neo-inositol, scyllo-inositol, d-chiro-inositol, l-chiroinositol and d-pinitol, and

at least one ingredient which increases nitric oxide production in the body.

- 11) It is my opinion that one of ordinary skill in the art in the fields of nutrition and nutritional supplementation would understand that term “whey” alone and in the context of the expressions “whey protein” and “whey peptides” to mean whey derived from a dairy source.
- 12) My opinion is based, in part, on the fact that commercially available “whey proteins” and “whey peptides” are commonly derived from milk and other dairy sources. As representative examples, attached to this declaration are Product Descriptions of *BiPRO®* Whey Protein Isolate (Davisco Foods International, Eden Prairie MN) (Exhibit A); and ALACEN 450 Whey Protein Concentrate (Clover/Fonterra, Roodepoort, South Africa) (Exhibit B).
- 13) To the best of my knowledge and information, all commercially available “whey proteins” and “whey peptides” are derived from milk and other dairy sources.
- 14) Thus, in my opinion one of ordinary skill in the art in the fields of nutrition and nutritional supplementation would understand that “whey” to mean “dairy whey”.
- 15) Furthermore, it is my opinion that the method claims counsel seeks to submit are directed to users (e.g. typically bodybuilders) who would practice the inventive methods of the present application.
- 16) It is my opinion that a user, such as bodybuilder, would understand that “whey” means whey derived from a dairy source.

17) Thus, in my opinion a user would also understand that “whey” means “dairy whey”.

The undersigned declares that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the life so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States code and this such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date:

March 23, 2009



Mr. Ken Clement



Exhibit A

DAVISCO

FOODS INTERNATIONAL, INC.*

BiPRO®

Whey Protein Isolate

Product Description

BiPRO is manufactured from fresh, sweet dairy whey that is concentrated and spray dried. The product is a homogenous, free flowing, semi-hygroscopic powder with a clean, bland flavor.

Product Functionality

BiPRO is a unique, natural and pure dairy protein comprised of beta-lactoglobulin and alpha-lactalbumin. BiPRO's functional protein groups have valuable gelling, water binding, emulsification and aeration properties. BiPRO replaces larger quantities of other functional ingredients providing improved flavor and mix efficiency. BiPRO is not denatured and is fully soluble over the pH range 2.0 to 9.0. BiPRO is lactose-free.

<u>Analysis*</u>	<u>Specification</u>	<u>Typical Range</u>	<u>Test Method</u>
Moisture (%)	5.0 max.	4.8 ± 0.2	Vacuum Oven
Protein, dry basis (N x 0.88) (%)	95.0 min.	97.8 ± 0.2	Leco Combustion
Fat (%)	1.0 max.	0.4 ± 0.2	Mojonnier
Ash (%)	3.0 max.	2.0 ± 0.2	Residue on Ignition
Lactose (%)	1.0 max.	< 0.5	By Difference
pH	6.7 - 7.5	7.0 ± 0.2	10% Sol. @ 20°C.
Scorched Particles	15 mg/25g max.	7.5mg	ADPI
<u>Microbiological Profile</u>	<u>Specification</u>	<u>Typical Range</u>	<u>Test Method</u>
Aerobic Plate Count	10,000/g max.	< 2,500	Standard Methods**
Coliform (MPN)	10/g max.	< 10	FDA/BAM
E. coli (MPN)	Negative/g	Negative	FDA/BAM
Yeast & Mold	10/g max.	≤ 10	Standard Methods**
Coag. Pos. Staph (MPN)	< 10/g	< 10	FDA/BAM
Salmonella sp.	Negative/1500 g	Negative	AGAC/ ELISA
Listeria sp.	Negative/25 g	Negative	AGAC/ ELISA

* All results reported on "AS IS" basis except where noted.

** Standard Methods for the Examination of Dairy Products, 16th Edition.

Storage and Packaging

Dried dairy products can absorb odors and moisture. Therefore, adequate protection is essential. Shelf life will be enhanced through ideal storage conditions which include temperatures below 25°C., relative humidity below 65%, and an odor free environment. Avoid less than ideal storage conditions.

Packaged in Kraft multiwall bags incorporating a polyethylene bag liner, individually closed.

Net wt: 33 Lbs.

version 07L-0108

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